INDIVIDUAL'S HEALTH – Clinical Outcomes Studies

PIH1

ASSESSMENT OF LENGTH OF STAY FOR WOMEN WITH HIGH RISK COMORBIDITIES DURING LABOR AND DELIVERY

Patel AM, Syeda SS, Wu WK
St. John's University, Queens, NY, USA

OBJECTIVES: Chronic co-morbid conditions during pregnancy have been associated with poor maternal and infant health. Although studies have shown that women with anemia, diabetes or thyroid dysfunction during pregnancy are at high risk of complications in delivery, little is known about their impact on the length of hospitalization. The objective of this study was to identify the increased Length of Stay (LOS) of pregnant women with these high-risk comorbidities compared with other comorbidities, hospitalized for delivery and labor in the US. **METHODS:** The 2006 National Hospital Discharge Survey (NHDS) was used as data source for the study. ICD-9-CM codes were reviewed to extract records of women with comorbid complications during labor and delivery (660.0–669.9) and to further identify women with high-risk comorbidity of anemia (648.0), diabetes (648.2) or thyroid dysfunction (648.1) complicating pregnancy, childbirth, and the puerperium. Survival analysis alongwith log rank test was used to evaluate the differences of LOS between patients with high risk comorbidities and low risk comorbidities. **RESULTS:** The 2006 NHDS recorded data for a total of 23,941 women with complications in delivery and labor. Among these, 2,490 women had high risk comorbidities while 21,451 women had other comorbidities complicating their delivery and labor. The median LOS for women with high risk comorbidities (3 days) was 1 day higher compared to pregnant women with other co-morbidities (2 days; $p = 0.001$). **CONCLUSIONS:** This study provides empirical data on LOS for women with high risk comorbidities in the course of labor and delivery. This result can be used as a basis by hospitals to assess their precautionary guidelines in pregnant women with high risk comorbidities to avoid additional LOS. Further research can be performed to investigate the impact of demographic characteristics and source of payment on the LOS of pregnant women with high risk comorbidities.

PIH2

CLINICAL AND COST OUTCOMES AMONG PATIENTS ON WARFARIN WITH ELECTRONIC ALERTS TO REMIND PROVIDERS ABOUT HIGH INTERNATIONAL NORMALIZED RATIO

Selvan MS, Peymann P, Flowers P, Murphy R, Shabot M
Memorial Hermann Healthcare System, Houston, TX, USA

OBJECTIVES: To understand benefits and risks of backing out of an alert for warfarin administration when high International Normalized Ratio (INR). Adverse drug events cause clinically significant adverse outcomes and complications 1–3. Analyses of a national surveillance study of showed that there were more than 175,000 visits for adverse drug events yearly, among them warfarin topped the list as the most commonly implicated medications. Such events are a huge economic burden to the nation impacting patients in a myriad different ways. Therefore, it is widely thought that mitigating warfarin related complications could help decrease medical expenses. **METHODS:** We developed an alert for our computerized pharmacy order system for all patients being treated with warfarin. The system generated an alert during the ordering of warfarin if the INR was ≥3.5. Upon encountering an alert providers had options such as back out from an order, or override, or override with some action. From June 1, 2007, to November 30, 2008, our system had 12,041 inpatient encounters and received 21,234 orders for warfarin. We had 820 alerts for a total number of 635 encounters. The mean warfarin dose was 4.76 mg. The mean INR for the 635 encounters with alert was 4.24 with a standard deviation of 1.69. **RESULTS:** Average length of stay, average cost per case and complications were significantly lower among patients whose providers cancelled warfarin orders than patients who received by ignoring the alert. In addition, providers who backed out from giving warfarin were more likely to prescribe vitamin k which may have helped mitigate complications. There was no statistical significance in the hematoma related complications (1.7% versus 2.0%) between backed out and overridden groups. **CONCLUSIONS:** Further investigation with additional factors is required before attributing the reduction in length of stay to backing out of an alert.

PIH3

SYSTEMATIC LITERATURE REVIEW OF THE GYNECARE PROLIFT® PELVIC FLOOR REPAIR SYSTEM TREATMENT OUTCOMES

Sikirica V[1], Robinson D[1], Kirkemo A[1], Hinoul P[2], Meek J[1], Jones SH[1], Perkins HE[1]
[1]Ethicon, Inc a Johnson & Johnson Company, Somerville, NJ, USA, [2]Ethicon, Inc a Johnson & Johnson Company, CEDEX, France

OBJECTIVES: To summarize the efficacy/effectiveness, complications and patient reported outcomes associated with the polypropylene mesh kit GYNECARE Prolift® Pelvic Floor Repair System. **METHODS:** A systematic literature review was conducted using MEDLINE, PUBMED and gynecologic conference abstracts from AUGS, IUGA and SGS for primary research focusing on the use of GYNECARE Prolift® from 2005–2008. Included studies needed to report on outcomes after any GYNECARE Prolift® regarding efficacy/effectiveness or safety of Anterior, Posterior or Total Repair. Single case studies, review articles, meta-analyses, non-English language studies and small case series ($n < 10$) were excluded. Kin study results were included only from the primary article. Weighted averages and confidence intervals were calculated. **RESULTS:** Among 33 independent studies included, mean (SD) follow-up time was 7.2 (4.6) months (95% CI: 7.0–7.4) among 24 studies reporting mean; and median follow-up reported was 7–19 months (data range: 2–30) for 9 studies. Objective anatomic success rates were 89.5% (95% CI: 88.2–90.6; n = 2614) for all GYNECARE Prolift®, and 89.5% (86.5–92.0; n = 532) for anterior, 92.0% (88.8–94.5; n = 386) for posterior and 91.3% (87.6–94.2; n = 311) for total repairs, respectively. Overall recurrence rate (any compartment) was 9.3% (8.2–10.6; n = 2217). Complication rates were: overall rate of any injury (Bladder, Bowel, Vaginal or Urethral) 1.7% (1.4–2.2; n = 4,750) of which bladder injury/perforation was the highest relative to other rates: 2.3% (1.8–3.0; n = 2486). Exposure rates were 6.9% (6.0–7.8; n = 2985). Mesh excision/ resection was reported at 6.4% (5.1–8.1; n = 1087). Dyspareunia rates were 6.7% (5.3–8.3; n = 1092). Patient satisfaction was 82.3% (77.0–86.9; n = 244) and 87.5% reported they would "recommend to a friend" (81.0–92.4; n = 144). **CONCLUSIONS:** The evidence for mesh-based repairs is growing. While more randomized, and appropriately powered trials are needed to understand longer-term outcomes, current peer-reviewed data shows that the GYNECARE Prolift® kit is an effective pelvic floor repair device with limited complications and high patient satisfaction.

PIH4

PERSONALIZED MEDICINE: TRENDS IN CLINICAL STUDIES BASED ON NATIONAL REGISTRY DATA

Nellesen D, Person A, Yee K, Chawla A
Analysis Group, Inc., Menlo Park, CA, USA

OBJECTIVES: Targeted therapies using pharmacogenomic data promise to improve the safety, efficacy, and cost-effectiveness of drug treatment significantly. To assess research progress in targeting biopharmaceutical interventions to address unmet medical need, we investigated therapeutic, temporal, and economic trends in personalized medicine using data from a national clinical trial registry. **METHODS:** Personalized medicine (PM) is the use of a patient's genotype or other molecular diagnostic (pharmacogenomic) data to guide a treatment decision. We queried ClinicalTrials.gov for studies using pharmacogenomic criteria for inclusion or exclusion, or for stratifying outcomes, restricting our analysis to Phase III or IV studies initiated on or before January 7, 2009. We verified the sensitivity of our search strategy using a known set of studies for which PM-related trials have been conducted. **RESULTS:** As a result, 1.7% (N = 155) of registered Phase III/IV trials in the US (N = 9,111) used pharmacogenomic data. Over time, the number of trials using pharmacogenomic data has increased greatly and, as expected, most PM trials (55%) were in the therapeutic areas of oncology and hematology. However, we observed a marked increase in the number of PM trials for drugs targeting disorders with highly variable treatment response, such as neurology and mental health disorders including Alzheimer's, depression, and schizophrenia. In addition, we found that the source of funding for PM trials increasingly comes from the pharmaceutical industry rather than from public sources. **CONCLUSIONS:** Targeting drugs to smaller subgroups is assumed to result in treating those patients most likely to respond and least likely to experience an adverse event. These data are consistent with the idea that these gains will be experienced broadly across therapeutic areas, however, the degree of impact will vary according to our understanding of the molecular basis of disease, with associated implications for assessing relative clinical and cost effectiveness.

PIH5

AN ANALYSIS OF SELECT INJURY-INCREASING ANALGESIC MEDICATIONS IN MEDICARE DUAL ELIGIBLE ENROLLEES

Blackwell SA, Montgomery MA, Baugh DK, Ciborowski G, Levy JM
Centers for Medicare & Medicaid Services, Baltimore, MD, USA

OBJECTIVES: To assess the risk of injury associated with the use of select analgesics in the elderly. **METHODS:** Logistic regression analysis performed to examine the risk of injury-related ER visits following the use of select analgesic medications. Demographic characteristics of CMS-HCC risk score, age, gender, and origin are reported as regressors. **RESULTS:** Separate analyses performed to assess the likelihood of an injury-related emergency room visit when the reference group under study was morphine, methadone, and propoxyphene recipients. For morphine, all medications analyzed were found to have a higher likelihood of an injury-related ER visit as compared to morphine, except for fentanyl ($p > 0.05$). Coding methadone as the reference group, only ketorolac, pentazocine and meperidine recipients had a higher likelihood of having an injury-related ER visit as compared to recipients of methadone (OR 1.411, 95% CI 1.301–1.530; OR 1.183, 95% CI 1.089–1.284; and OR1.181, 95% CI 1.097–1.273, respectively). Designating propoxyphene as the reference group, only ketorolac, pentazocine, meperidine, methadone, and hydrocodone recipients had a higher likelihood (OR 1.470, 95% CI 1.367–1.581; OR 1.232, 95% CI 1.144–1.327; OR 1.231, 95% CI 1.153–1.314; OR 1.042, 95% CI 1.004–1.081; OR 1.047, 95% CI 1.038–1.057, respectively). Regarding demographics, Caucasian origin, male gender, middle-age elderly, and high CMS-HCC risk scores were found to be factors influencing injury-related ER visits for elderly analgesic recipients. **CONCLUSIONS:** Morphine is a very suitable opioid for use in the elderly. Methadone, a non-Beers medication, is a problematic opioid needing further assessment by the clinical community for possible assignment to the Beers list. Propoxyphene, currently a low severity rated Beers medication, needs further assessment for possible reassignment to a high severity rating.